

CDPH/CTCA JOINT GUIDELINES 2009

Guidelines for the Follow-Up and Assessment of Immigrants and Refugees with a Class A/B Tuberculosis Notification

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PREFACE

The following Guidelines have been developed by the California Department of Public Health (CDPH), Tuberculosis Control Branch (TBCB) and the California TB Controllers Association (CTCA). These Guidelines provide statewide recommendations for tuberculosis control in California. If these Guidelines are altered for local use, then the logo should be removed and adaptation from this source document acknowledged.

No set of guidelines can cover all individual situations that can and will arise. When questions arise on individual situations not covered by these guidelines, consult with your local TB Controller or TBCB.

Note, as of October 1, 2009, the 2007 Technical Instructions were further revised and can be found on the CDC website at <http://www.cdc.gov/ncidod/dq/pdf/tuberculosis-ti-2009.pdf>

PURPOSE

The overall goal of these guidelines is to promote prompt detection of tuberculosis (TB) disease among newly arriving immigrants and refugees and prevention of future cases.

BACKGROUND

In 2008, almost one-third of foreign-born tuberculosis (TB) cases in the United States were diagnosed in California, and more than three quarters of all California cases were among the foreign-born. From 2007-2008, 10,825 of 30,017 (36 percent) new immigrants with a class B TB notification to the United States (US) had California as their destination. Recommendations from the Centers for Disease Control and Prevention (CDC) and the Advisory Council for the Elimination of Tuberculosis (ACET) have emphasized the screening of immigrants and refugees from areas of the world with a high prevalence of TB as a critical opportunity for TB case detection and prevention.

Overseas pre-immigration screening is a strategy to identify immigrants and refugees at risk for TB disease. This overseas screening and notification process is designed to exclude immigrants or refugees with infectious TB from entering the United States, and to ensure that recent arrivals with active or latent TB infection receive medical services. The systematic and efficient implementation of the TB notification program in each jurisdiction will enhance the timely evaluation of immigrants and refugees for TB. The prompt treatment of any active cases discovered will protect the public by lessening the likelihood of TB transmission in the community.

It is essential for tuberculosis control programs to have an effective strategy for identification and evaluation of immigrants and refugees with TB notification. During 2005-2008, a total of 17,858 immigrants and refugees with a TB notification arrived in California, and three to seven percent were diagnosed with active TB within one year of arrival. These active TB cases represented nearly 5 percent of incident cases in California during that time period, and in California, 35 percent (2001-2007 average) of foreign-born TB cases diagnosed within a year of US arrival are persons with a TB notification.

In terms of the number of active TB cases detected, the yield of follow-up of persons with a TB notification (40 cases per 1000 immigrants evaluated) exceeds that of contact investigation (10 cases per 1000 contacts evaluated). TB notification follow-up also provides TB programs an important means to prevent future cases since approximately 40 percent of persons evaluated

have inactive TB (TB4) or TB infection (TB2) for which treatment is indicated¹. While this immigration screening program may not result in an immediate large decline in US cases, domestic follow-up of persons with TB notifications, including latent tuberculosis infection (LTBI) treatment, is highly cost-effective.²

Overseas Screening and Treatment

The CDC provides direction and technical assistance to panel sites throughout the world that are charged with medical screening of applicants for permanent residence in the US. The screening includes a TB assessment. The technical instructions (TIs) for screening and medical exam for TB have recently been enhanced and are available at: <http://www.cdc.gov/ncidod/dq/pdf/tuberculosis-ti-2009.pdf>³. The revised TIs published in 2007 are being implemented in a stepwise manner. At this point in time both the newly revised TIs (2007) and the previous TIs issued in 1991 are in operation in different countries globally. The countries currently using the new TIs are listed at http://www.cdc.gov/ncidod/dq/panel_2007.htm. Below is a description of both old and new instructions that guide panel physicians in TB screening procedures. Notably, the new instructions have an increased sensitivity for case detection through use of sputum culture in addition to smear.

Under the 1991 CDC Technical Instructions for Tuberculosis Screening, applicants over the age of 14 receive a chest radiograph (CXR) overseas before traveling to the United States. If the CXR suggests active TB, sputum smears are obtained and the applicant is classified as shown in Appendix 1.

In 2007, CDC released new TIs for TB assessment. A major change in the screening algorithm is that patients who are suspected to have TB based on the immigration CXR or clinical exam are required to have sputum smears, cultures, and susceptibility testing. Treatment is to be completed using directly observed therapy (DOT) prior to immigration. Patients are not to be cleared for travel until sputum cultures are negative. In addition, under the new TIs, those aged 2-14 are screened with tuberculin skin test (TST). If the reaction is 5 mm or greater a CXR must be done; if active disease is ruled out, these children are classified as B2. Contacts to known cases in the applicant's family or living group are also screened with TST and classified as B3. The instructions and comparison tables of the 1991 and 2007 TI are published at: http://www.cdc.gov/ncidod/dq/panel_2007.htm. Appendix 2 shows the screening steps used under the 2007 TIs. The 2007 tuberculosis classifications, as well as a comparison table of the classification used in TI 1991 and TI 2007, are shown in Appendix 3.

Please be aware that the CDC guidance for panel physicians who conduct overseas screening differs significantly from the guidance for civil surgeons who screen persons already in the U.S. adjusting their visa status. The civil surgeons guidelines are available at http://www.cdc.gov/Ncidod/dq/civil_tb_ti_2008.htm.

Waivers

Persons with Class A conditions cannot enter the US unless they have a waiver. Infectious TB is a class A condition. The waiver provision allows applicants undergoing treatment for pulmonary or laryngeal tuberculosis to petition for entry. Waivers can be pursued by any immigrant or refugee who can show that they have a compelling medical or social reason for entry. The health officer in the receiving jurisdiction must agree to accept an individual with a waiver. Waivers are not frequently pursued. Applicants suspected of having culture negative tuberculosis disease do not need to obtain a waiver to enter the US.

Receipt of Class B TB notifications (B notification)

Local Health Jurisdictions (LHJ) may receive B notifications from a variety of sources including the following:

1. Electronic B notifications via the CDC web-based B notification reporting system (Electronic Disease Notification - EDN)
2. Paper copies of B notifications and overseas medical forms mailed from California Department of Public Health/ Tuberculosis Control Branch (CDPH/TBCB)
3. Immigrants/refugees who walk in for evaluation without prior notice of B notification with or without their paperwork
4. Transfers from other jurisdictions and states (may be electronic or paper notification)

Domestic Follow-Up

When a person with Class A/B1 TB moves to the United States, the LHJ is notified electronically via the EDN. For jurisdictions not participating in the web-based notification network, notifications are typically received by mail or fax from their state health department. The immigrant is instructed by the staff at the federal quarantine station at the port of entry to report to the LHJ within one month of arrival.

Receiving Notifications and Reporting Domestic Outcomes: EDN

EDN is a national web-based system developed and supported by CDC that provides overseas TB screening and treatment information and domestic follow-up information. EDN is able to produce reports on individuals and groups of immigrants and refugees.

At quarantine stations, A/B notification paperwork is retrieved from applicants and sent to the CDC where the data is entered into EDN. The notification is then automatically sent to participating LHJs. The LHJs who have EDN access obtain necessary information electronically and contact the patient for an appointment. Domestic TB evaluation results are entered into EDN by participating local and state health department staff. EDN can be used to generate select reports and examine outcomes of TB evaluations. The Tuberculosis classification coversheet that now comes with the A/B notification paperwork is shown in Appendix 4. The EDN B Notification follow-up worksheet, which is filled out by Local Health Jurisdictions to report domestic TB evaluation results, is included in Appendix 5.

RECOMMENDATIONS FOR FOLLOW-UP AND ASSESSMENT OF PERSONS WITH CLASS B1/B2 TUBERCULOSIS

Prioritization and Evaluation of Persons with Different TB Notification Classes

Priority 1: Class A (1991 and 2007 TIs)

Persons who arrive with a class A waiver are persons with known infectious TB. This group represents the highest priority for prompt evaluation. This group is likely to remain a very small fraction of arrivers with TB notifications.

Priority 2: Classes B1 and B2 (1991 TIs), and Class B1 (2007 TIs)

The next priorities for evaluation are persons with B1 and B2 classifications who were screened in countries that are still using the 1991 TIs. Those with a B1 classification under the 2007 TIs should also be prioritized. Priority group 2 includes untreated TB cases, culture-negative TB suspects, extrapulmonary TB, and treated TB cases that may relapse. It is critical for programs to focus available resources on prompt evaluation of these persons.

Priority 3: Classes B2 and B3 (2007 TIs)

The next priorities for evaluation are those with Latent Tuberculosis Infection (LTBI) (B2 2007 class) and contacts (B3 2007 class).

Of note, those arriving with any B (B1 or B2) classification who were screened in countries that have not implemented the enhanced screening (2007 TIs) with TB culture represent a high priority for domestic evaluation. The 1991 instructions require acid-fast bacilli (AFB) smear only for case detection and thus we expect more cases identified with use of culture in the US for those applicants/B waiver cases coming from countries still using the 1991 guidelines. For this reason, persons with B notifications screened before implementation of the enhanced instructions should be prioritized over those screened under the 2007 TIs. Operationalizing this prioritization may vary by jurisdiction and will be influenced by the local health jurisdiction care structure and available resources.

ENSURING RAPID NOTIFICATION AND FOLLOW-UP OF PERSONS WITH TB NOTIFICATIONS

- A. Due to the mobility of many newly arrived immigrants and refugees, local TB program staff should attempt to locate and evaluate individuals as soon as possible following their arrival. Also, efforts to locate and evaluate individuals with B notification quickly are likely to be more cost effective than TB treatment and extensive contact investigations if they are later discovered to have disease.
 - 1- LHJ staff should initiate follow-up within 14 days of receipt of notification.
 - 2- If attempts to contact the new entrant are unsuccessful within 14 days, a home visit is recommended depending on LHJ resources and notification category priority.
- B. Recommended activities for locating persons with TB notifications are as follows:
 - 1- TB control and local health programs should use a variety of active outreach strategies to locate persons with TB notifications, depending on available

resources, which may include letters, telephone calls, and home visits. A sample letter from a TB program to a new arriver with a TB notification is shown in Appendix 6.

- 2- Effective communications can promote greater patient trust and improve evaluations and treatment outcomes. Thus the following should be considered when making contact with the patients:
 - a) Outreach strategies should consider the language and cultural needs of newly arrived persons. For example, whenever possible, public health staff who speak the person's primary language should telephone the new arrival. (Note. The CDC notification form specifies country of birth).
 - b) Any correspondence should ideally be written in English and the patient's primary language.
 - c) Public health staff who do not speak the patient's language should be teamed with a trained and culturally sensitive interpreter whenever feasible.
- 3- If a person has moved, obtain new locating information (e.g., home address and telephone number, place of employment). LHJ staff may obtain this information from a variety of sources, including the person's sponsor, family members, the local post office, community based organizations, or voluntary agencies. If locating information is missing, the program may contact TBCB for assistance. Information collected on movement should be entered into EDN or contact CDPH and the destination county.
- 4- If the person has already returned to his/her country, ask sponsor/family/friends to notify LHJ staff if the person returns to the U.S. In some LHJs, staff will periodically (e.g. monthly for six months) call or visit the person's family or friends to determine if (s)he has returned. This is dependant on LHJ resources and priority of TB notification category. The information should be relayed to TBCB and CDC via EDN.
- 5- For high priority persons, LHJ staff can use incentives (e.g., grocery vouchers, etc.) to improve adherence with follow-up.
- 6- If the individual cannot be located or fails to make contact with the health department or refuses examination, the LHJ should consider requesting, where available, the assistance of local or state public health field investigators, voluntary agencies, and community-based organizations. LHJs may also consider using legal orders if a TB suspect requires evaluation.

ENSURING ADEQUATE EVALUATION AND TREATMENT OF PERSONS WITH TB NOTIFICATIONS

The primary goal of the evaluation of immigrants with A/B classification is to ensure that all active TB cases are identified. A secondary goal is to identify persons with latent TB infection (LTBI) who are eligible for treatment to prevent progression to active disease.

In many LHJs immigrants and/or refugees with TB notifications are evaluated at local TB program or refugee clinics. When this is not possible, the LHJ should work with the private sector to assure evaluations are performed according to latest recommendations. Domestic

evaluations of newly arrived immigrants should also be guided by and based on an understanding of the overseas TIs and the implications of follow-up for the control of TB in the U.S.

- A. Evaluation of individuals with any B notification should include:
- a. Review of the overseas paperwork and patient interview to determine pertinent history, including known TB exposures, treatment, and any testing performed for TB disease and TB infection and relevant co-morbidities.
 - b. Review of overseas CXR(s).
 - c. Identification of missing or incomplete paperwork. Missing information should be noted, and additional information sought from the appropriate Panel physicians via CDPH and CDC. Please contact the CDPH TB Notification Epidemiologist with these requests.
 - d. Perform an evaluation that includes sputum cultures on all immigrants and refugees with an abnormal CXR suggestive of TB. This is of paramount importance to identify active TB and interrupt transmission.
- B. Specific evaluation recommendations:
- a. Culture-proven TB, treated overseas (pre-entry): Under the 2007 TIs, culture-proven TB must be treated to completion following US standards of treatment, under conditions of DOT. However, circumstances may exist where the exact treatment conditions cannot be verified in the country of origin. Until sufficient data becomes available on newly arriving immigrants treated and screened overseas, a cautious approach to evaluation is recommended, as follows:
 - i. Assess the adequacy of overseas information (e.g. completeness of DOT documentation; appropriateness of treatment regimen for susceptibility pattern; documentation of culture conversion, etc.) Determine whether DOT was provided by panel site or provider outside of the panel site as the quality of DOT may vary by provider.
 - ii. Evaluate for current symptoms and perform a physical assessment.
 - iii. If overseas treatment appears adequate (e.g. consistent with ATS standards) and patient is without signs or symptoms of active disease.
 1. Repeat CXR if more than three months have elapsed since overseas CXR or if immigrant is human immunodeficiency virus (HIV) positive, immune suppressed, less than five years old, or if the overseas CXR is of poor quality or is unavailable.
 2. Collect three specimens for smear and culture on all patients with prior TB treatment. At this time the long term effectiveness of treatment at different panel sites is not known, and since relapse rates may exceed three percent, domestic follow-up including culture of those new arrivals treated for TB overseas is recommended.
 3. If CXR has worsened and suggests TB, start treatment and implement appropriate isolation measures.
 4. For those not started on TB treatment, schedule a follow-up appointment to repeat CXR, sputum cultures and evaluate for relapse. Repeat CXR and sputum cultures during the 6 – 12

month period following U.S. arrival at the intervals suggested below.

- i. For patients with non-extensive, non-multidrug resistant (MDR) TB disease treated prior to US entry, a follow-up appointment at one year post-arrival is recommended if resources permit.
 - ii. Follow-up evaluations every six months for two years are recommended if TB was extensive or multiple drug-resistant. Extensive disease is defined as bilateral, cavitary, multilobar pulmonary disease or disseminated to multiple noncontiguous sites. These evaluations should include collection of two sputum specimens at six-month intervals.
5. Immigrants should also be instructed regarding signs and symptoms of active TB and where to seek follow-up care, as needed.
- iv. If overseas TB treatment was not adequate or is not fully documented
 1. Repeat CXR.
 2. Collect three sputum samples for smear and culture.
 3. Follow-up: if sputa are all culture negative and treatment is not started follow-up evaluations at six month intervals for one year (for patients with a history of non-extensive, non-MDR TB), or two years (for patients with a history of extensive or MDR TB) is recommended; and may include collection of two sputum specimens at six-month intervals.
 4. Immigrants should also be instructed regarding signs and symptoms of active TB and where to seek follow-up care, as needed.
- b. Active TB, not treated overseas: Under the 1991 TIs, immigrants with class B1 and B2 TB are not required to have treatment prior to travel; under the 2007 TIs immigrants with class B1 TB may travel prior to treatment if they are culture negative or are suspected of extrapulmonary TB only.
 - i. For suspected extrapulmonary TB
 1. Evaluate for current signs and symptoms.
 2. Perform or refer for appropriate diagnostic testing (e.g. lymph node biopsy for cervical adenitis).
 3. Have a low threshold to repeat CXR.
 4. Start treatment based on clinical assessment and specimen results.
 - ii. For suspected pulmonary TB
 1. Evaluate for current signs and symptoms.
 2. Repeat CXR.
 3. If CXR is abnormal and consistent with possible TB, collect three sputum exams for smear and culture.
 4. Start treatment based on results of clinical assessment and/or culture results.

5. If treatment is not started, patients should be reassessed when culture results become final to assess disease class/activity.
 - iii. If active TB is ruled out by negative cultures and CXR is stable, LTBI treatment should be considered. Decisions about treatment for LTBI will depend on TST or IGRA findings and adequacy of any previous treatment. If LTBI treatment is not started, patient should be educated about signs and symptoms of TB and risk of future TB. Guidelines on testing and treatment for LTBI are available at <http://www.ctca.org/guidelines/IIA2targetedskintesting.pdf>.
 - iv. If suspicion for active TB remains after negative cultures, empiric treatment for clinical TB with four anti-TB drugs should be considered, with reassessment performed at two to three months to determine whether response to TB treatment occurred.
- c. Latent TB Infection: Under the 2007 TIs, children 2-14 years of age who have a TB skin test measuring $\geq 10\text{mm}$ and whose CXRs are without evidence of active TB, are classified as B2, LTBI. For arrivals with B2, LTBI class, consider repeating CXR under the following circumstances. If >3 months since overseas CXR, repeat CXR if the patient is a child <5 years of age, is immunocompromised, or has symptoms of TB. If >6 months since overseas CXR, repeat CXR if LTBI treatment will be started.

Programs may consider the following options for follow-up based on accessibility of testing and program resources.

- Option 1. Treat for LTBI based on overseas TST result.
- Option 2. Re-test with a TST for verification of overseas reading.
- Option 3. Test with IGRA (Interferon-gamma release assay).
 1. If IGRA is positive, treat for LTBI.
 2. If IGRA is negative, do not treat.
 3. Specific factors to consider in treatment decisions include: TST induration >15 mm, overseas BCG receipt, time since BCG vaccine, and recent TB exposure.

Children < 15 with class B2, LTBI may be referred to private providers for evaluation and treatment based on public health priorities and resources. Ideally the health department would track the final American Thoracic Society (ATS) classification.

- d. Contacts: Under 2007 TIs, persons with a B3 classification are persons who had close household exposure to a smear or culture-confirmed pulmonary case of TB and a TST $\geq 5\text{mm}$ or have a TST $< 5\text{mm}$ but have not yet had repeat testing at eight weeks post-exposure. Contacts <3 years old or immunocompromised may have started LTBI therapy prior to immigration.

Immigrants with a B3 classification should be interviewed regarding timing, setting, and last date of exposure. Review information about the suspected source case including smear, culture and susceptibility results.

1. If exposure is confirmed or appears likely, and the TST ≥ 5 mm, treat for LTBI as per current recommendations and based on suspected source case susceptibilities.
2. If source case information is not available, contact the California TB Control Branch to retrieve available information from CDC.
3. If exposure is not confirmed or seems unlikely and TST ≥ 10 mm, proceed as described in Latent TB Infection section above (Page 8, section B,c under “Ensuring adequate evaluation and treatment of persons with B notifications”). Decisions to offer LTBI treatment should be based on local resources and priorities.
4. If IGRA is performed and the result is negative in BCG vaccinated individuals, some programs may elect not to treat.
5. Window prophylaxis is not indicated for most immigrants with a B3 classification, since the time following overseas TB exposure has frequently exceeded 10 weeks.

TRACKING AND MANAGING INFORMATION

LHJs should establish a mechanism to effectively log, track, and evaluate B notification follow-up. To accomplish this, it is generally helpful to receive and process TB notifications and follow-up information in a central coordinating location. High morbidity LHJs may find it helpful to designate one person such as a TB notification clerk to be the central contact person. In jurisdictions where there is a separate refugee program, it may act as a separate collection and coordinating point for refugees.

Those programs who participate in EDN for notification and reporting in California may utilize EDN for tracking and reporting. Health departments which do not participate in EDN receive notifications by fax or mail from TBCB. Domestic evaluations should be returned to TBCB by EDN, fax or mail, within 90 days of U.S. entry.

NATIONAL AND STATE STANDARDS FOR FOLLOW-UP AND EVALUATION

National Indicators

CDC/NTCA (National Tuberculosis Controllers Association) workgroup has proposed national indicators for TB Notification follow up, which are detailed in Appendix 7.

TB Notification Goal

All newly arrived refugees and immigrants with Class A/B1 TB will receive thorough and timely TB evaluations and appropriate treatment to ensure prompt detection of TB disease and prevention of future cases.

TB Notification Objectives

LHJs should set realistic local objectives for the domestic evaluation indicators in Appendix 8 and measure program performance against these established targets on at least an annual basis.

Outcome Reporting

All LHJs should evaluate their performance in meeting objectives. To accomplish this, LHJ staff may want to record and track all TB notifications received in a registry or log. The EDN reporting system also allows for data output and creation of a log/registry. Documentation should reflect information that will be evaluated or otherwise meets local needs and may include the information in Appendix 9. LHJs that participate in EDN can produce indicator reports and TB evaluation outcomes to examine timeliness of evaluation and reporting.

FINAL FORMATTING PENDING

RESOURCES

1. Link to EDN Frequently Asked Questions (FAQs)

<http://cdphinternet/programs/tb/Documents/B-note%20EDN%20FAQs.pdf>

2. Points of contact for assistance with EDN

EDN Help desk – CDC
Telephone: (866) 226-1617
Email: edn@cdc.gov

Assistance – TBCB
TB Notification Epidemiologist
Surveillance and Epidemiology Section
Telephone: (510) 620-3000

3. Troubleshooting/Questions about B Notification and EDN

The EDN helpdesk should be contacted for assistance with the following types of questions/problems:

- 1) Expired password
- 2) System performance (i.e. EDN system runs slowly or crashes)
- 3) Obtaining and/or installing a digital certificate
- 4) Inability to access the Secure Data Network (SDN) (overarching CDC data system which includes the EDN application)

The TBCB should be contacted for assistance with the following types of questions/problems:

- 1) Missing Department of State (DS) forms (DS) (DS-2053, DS-3024, DS-3026) for B-notification arrivals
- 2) Incomplete/incorrect information on the DS forms
- 3) Questions about using the functions in the EDN system
- 4) Requests for training for EDN users at local health jurisdictions
- 5) Requests to add or remove EDN users at a local health jurisdiction

REFERENCES

1. Sciortino S, Mohle-Boetani J, Royce SE, Will D, Chin DP. B notifications and the detection of tuberculosis among foreign-born recent arrivals in California. *Int J Tuberc Lung Dis*. 1999 Sep; 3(9):778-85.

http://docstore.ingenta.com/cgi-bin/ds_deliver/1/u/d/ISIS/49395357.1/iatld/ijtld/1999/00000003/00000009/art00008/E746F06F1BBBF6041236898741D0948E244C0FED26.pdf?link=http://www.ingentaconnect.com/error/delivery&format=pdf

2. Porco TC, Lewis B, Marseille E, Grinsdale J, Flood JM, Royce SE. Cost-effectiveness of tuberculosis evaluation and treatment of newly-arrived immigrants. *BMC Public Health*. 2006 June 19; 6:157.

<http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1559699&blobtype=pdf>

3. CDC. Notice to Readers: Revised Technical Instructions for Tuberculosis Screening and Treatment for Panel Physicians. *MMWR Weekly* March 21, 2008; 57(11); 292-293.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5711a5.htm>

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FINAL FORMATTING PENDING

APPENDICES

Appendix 1

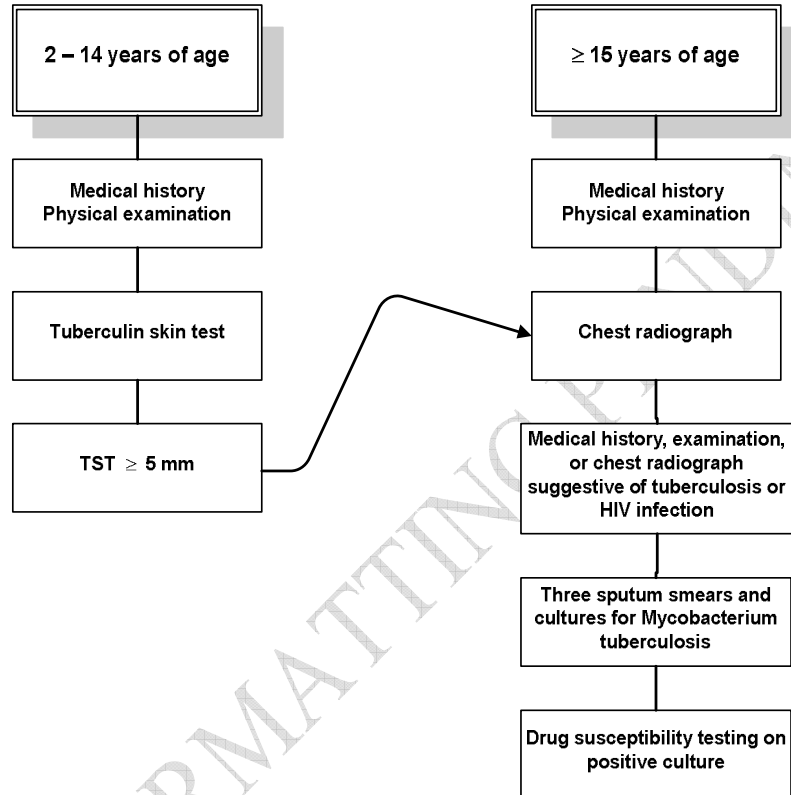
1991 A/B Classification System

Immigrant/ Refugee Classification	Overseas CXR	Overseas Sputum AFB Smears	Restrictions
A Waiver *	Abnormal, suggestive of active TB	Positive	May not enter the U.S. until started on anti-TB therapy and sputum smears are negative and: 1) Apply for a waiver signed by the local health department in their intended U.S. destination (A waiver), or 2) Complete TB therapy overseas
B1	Abnormal, suggestive of active TB	Negative	Instructed to report to the local health department in the US for further medical evaluation within 30 days of arrival
B2	Abnormal, suggestive of inactive TB	Not done	Same as above

Appendix 2

Tuberculosis screening medical examination for applicants in countries with a WHO-estimated tuberculosis rate of ≥ 20 cases per 100,000 population

Source: CDC Immigration Requirements: Technical Instructions for Tuberculosis Screening and Treatment 2007



Appendix 3

2007 Tuberculosis Classifications and Descriptions

Classification	Description
No TB Classification	Applicants with normal tuberculosis screening examinations.
Class A TB With waiver	All applicants who have tuberculosis disease and have been granted a waiver.
Class B1 TB Pulmonary	<ul style="list-style-type: none">• No treatment<ul style="list-style-type: none">○ Applicants who have medical history, physical exam, HIV, or CXR findings suggestive of pulmonary tuberculosis but have negative AFB sputum smears and cultures and are not diagnosed with tuberculosis or can wait to have tuberculosis treatment started after immigration• Completed treatment<ul style="list-style-type: none">○ Applicants who were diagnosed with pulmonary tuberculosis and successfully completed directly observed therapy prior to immigration.
Class B1 TB Extrapulmonary	Applicants with evidence of extrapulmonary tuberculosis. Document the anatomic site of infection.
Class B2 TB LTBI Evaluation	Applicants who have a tuberculin skin test ≥ 10 mm but otherwise have a negative evaluation for tuberculosis.
Class B3 TB Contact Evaluation	Applicants who are a recent contact of a known tuberculosis case.

Source: CDC Immigration Requirements: Technical Instructions for Tuberculosis Screening and Treatment 2007

Comparison of the classification used in TI 1991 and TI 2007

TB Class Description	1991 Technical Instructions	2007 Technical Instructions
Active TB, infectious	A with waiver	A with waiver
Active TB, non-infectious	B1/B2	B1
Latent TB infection (children ages 2-14)	--	B2
TB Contact	--	B3

Appendix 4

APPENDIX F		TUBERCULOSIS CLASSIFICATION COVER SHEET	
			/ /
Last name	First name	Alien Number	Birth Date (mm/dd/yyyy)
<i>Check all applicable classifications and subcategories*</i>			
<input type="checkbox"/> No TB Classification			
<input type="checkbox"/> Class A TB with waiver			
<input type="checkbox"/> Class B1 TB, Pulmonary <input type="checkbox"/> No treatment <input type="checkbox"/> Completed treatment (check all that apply) <input type="checkbox"/> Initial smear positive <input type="checkbox"/> Initial culture positive <input type="checkbox"/> Pre-treatment culture and DST results performed/available <input type="checkbox"/> Pre-treatment culture and/or DST results not performed/available			
<input type="checkbox"/> Class B1 TB, Extrapulmonary Anatomic site of disease: _____ <input type="checkbox"/> No treatment <input type="checkbox"/> Current treatment <input type="checkbox"/> Completed treatment			
<input type="checkbox"/> Class B2 TB, LTBI Evaluation <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> TST ≥10 mm (or ≥5 if HIV positive): _____ mm induration <input type="checkbox"/> Not started on LTBI treatment <input type="checkbox"/> Currently on LTBI treatment (<i>medications</i>): _____ <input type="checkbox"/> Completed LTBI treatment (<i>medications</i>): _____ </div> <div style="border: 1px solid black; padding: 5px; width: 150px;"> <input type="checkbox"/> TST conversion </div> </div>			
<input type="checkbox"/> Class B3 TB, Contact Evaluation TST Result: _____ mm induration <input type="checkbox"/> Not started on preventive treatment <input type="checkbox"/> Currently on preventive treatment (<i>medications</i>): _____ <input type="checkbox"/> Completed preventive treatment (<i>medications</i>): _____ Source case: Name _____ Alien Number _____ Relationship to contact _____ Type of source case TB (mark only one): <input type="checkbox"/> Pansusceptible TB <input type="checkbox"/> MDR TB (resistant to at least INH and rifampin) <input type="checkbox"/> Drug-resistant TB other than MDR TB <input type="checkbox"/> Culture negative <input type="checkbox"/> Culture results not available			
			/ /
Name of Panel Physician	Signature of Panel Physician	Date (mm/dd/yyyy)	

* Applicants may have more than one designated classification, e.g., they may be Class B1 Extrapulmonary, Class B2 TB, LTBI Evaluation, and Class B3 TB, Contact Evaluation.

Appendix 5

EDN B notification follow-up worksheet									
A. Demographic Information									
A1. Name (Last, First, Middle)				A2. Alien #:		A3. Visa Type:		A4. Initial U.S. Entry Date:	
A5. Age:		A6. Gender:		A7. DOB:		A8. TB Class:		A9. Class Condition:	
A10. Country of Examination:					A11. Country of Birth:				
A12. Data Entry Q-Station:			A13. Officer in Charge:				A14. Q-Station Phone:		
A15c.					A16a. Sponsor Agency Name:				
					A16b. Sponsor Agency Phone:				
					A16c. Sponsor Agency Address:				
B. Jurisdictional Information									
B1. Destination State:				B2. Jurisdiction:			B3. Jurisdiction Phone #:		
C. U.S. Evaluation									
C1. Date of Initial U.S. Medical Evaluation:									
C2a. TST Placed: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown C2b. TST Placement Date: _____ C2c. TST mm: _____ C2d. TST Interpretation: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown C2e. History of Previous Positive TST <input type="checkbox"/>									
C3a. Quantiferon (QFT) Test: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown C3b. QFT Collection Date: _____ C3c. QFT Result: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate <input type="checkbox"/> Unknown									
U.S. Review of Overseas CXR					Domestic CXR			Comparison	
C4. Overseas CXR Available? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Verifiable					C7. U.S. CXR Done? <input type="checkbox"/> Yes <input type="checkbox"/> No			C11. U.S. CXR Comparison to Overseas CXR: <input type="checkbox"/> Stable <input type="checkbox"/> Worsening <input type="checkbox"/> Improving <input type="checkbox"/> Unknown	
C5. U.S. Interpretation of Overseas CX <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Poor Quality <input type="checkbox"/> Unknown					C8. Date of U.S. CXR: _____				
C6. Overseas CXR Abnormal Findings: <input type="checkbox"/> Abnormal, not TB <input type="checkbox"/> Cavity <input type="checkbox"/> Fibrosis <input type="checkbox"/> Infiltrate <input type="checkbox"/> Granuloma(ta) <input type="checkbox"/> Adenopathy <input type="checkbox"/> Other (Specify) _____					C9. Interpretation of U.S. CXR: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown				
C10. U.S. CXR Abnormal Findings: <input type="checkbox"/> Abnormal, not TB <input type="checkbox"/> Cavity <input type="checkbox"/> Fibrosis <input type="checkbox"/> Infiltrate <input type="checkbox"/> Granuloma(ta) <input type="checkbox"/> Adenopathy <input type="checkbox"/> Other (Specify) _____									
C12. U.S. Microscopy / Bacteriology <input type="checkbox"/> Specimen not collected in U.S.									
Spec #	Specimen Source	Date	AFB Smear Result		Culture Result		Drug Resistance (DR)		
1			<input type="checkbox"/> Not Done	<input type="checkbox"/> Positive	<input type="checkbox"/> Not Done	<input type="checkbox"/> NTM	<input type="checkbox"/> Not Done	<input type="checkbox"/> Mono-RIF	
			<input type="checkbox"/> Negative	<input type="checkbox"/> Unknown	<input type="checkbox"/> Negative	<input type="checkbox"/> Contaminated	<input type="checkbox"/> No DR	<input type="checkbox"/> MDR-TB	
2			<input type="checkbox"/> Not Done	<input type="checkbox"/> Positive	<input type="checkbox"/> Not Done	<input type="checkbox"/> NTM	<input type="checkbox"/> Not Done	<input type="checkbox"/> Mono-RIF	
			<input type="checkbox"/> Negative	<input type="checkbox"/> Unknown	<input type="checkbox"/> Negative	<input type="checkbox"/> Contaminated	<input type="checkbox"/> No DR	<input type="checkbox"/> MDR-TB	
3			<input type="checkbox"/> Not Done	<input type="checkbox"/> Positive	<input type="checkbox"/> Not Done	<input type="checkbox"/> NTM	<input type="checkbox"/> Not Done	<input type="checkbox"/> Mono-RIF	
			<input type="checkbox"/> Negative	<input type="checkbox"/> Unknown	<input type="checkbox"/> Negative	<input type="checkbox"/> Contaminated	<input type="checkbox"/> No DR	<input type="checkbox"/> MDR-TB	
			<input type="checkbox"/> Negative	<input type="checkbox"/> Unknown	<input type="checkbox"/> MTB Complex	<input type="checkbox"/> Unknown	<input type="checkbox"/> Mono-INH	<input type="checkbox"/> Other DR	

EDN B notification follow-up worksheet

U.S. Review of Overseas Treatment

C13. Overseas Treatment
Recommended by Panel Physician:

- ☐ Yes
☐ No
☐ Unknown

C14. US Review of TB Disease
Overseas Treatment:

- ☐ Yes ☐ No ☐ Unknown
If Yes
☐ Patient-Reported
☐ Panel Physician-Documented
☐ Both

C15. Arrived on Treatment:

- ☐ Yes
☐ No
☐ Unknown

C16. Completed Treatment
Overseas:

- ☐ Yes
☐ No
☐ Unknown

C17. Overseas Treatment Concerns:

- ☐ Yes ☐ No

D. Disposition

D1. Disposition Date:

D2. Evaluation Disposition:

☐ Completed Evaluation

☐ Initiated Evaluation / Not Completed

☐ Did Not Initiate Evaluation

- ☐ Treatment Recommended
☐ No Treatment Recommended

- ☐ Moved within U.S.
☐ Lost to Follow-up
☐ Returned to Country of Origin
☐ Refused Evaluation
☐ Died
☐ Other, specify

- ☐ Not Located
☐ Moved within U.S.
☐ Lost to Follow-up
☐ Returned to Country of Origin
☐ Refused Evaluation
☐ Died
☐ Unknown
☐ Other, specify

D3. Diagnosis:

- ☐ Class 0 - No TB exposure, not infected ☐ Class 1 - TB exposure, no evidence of infection
☐ Class 2 - TB infection, no disease ☐ Class 3 - TB, active disease
☐ Class 4 - TB, inactive disease ☐ Pulmonary ☐ Extrapulmonary ☐ Both Sites

D4. ☐ RVCT Reported

D5. RVCT #:

E. U.S. Treatment

E1. U.S. Treatment Initiated:

- ☐ No Treatment
☐ Active Disease
☐ LTBI
☐ Unknown

E2. U.S. Treatment Start Date:

E3. U.S. Treatment Completed:

- ☐ Yes
☐ No
☐ Unknown

E4. U.S. Treatment End Date:

F. Comments

G. Physician Signature

_____ Panel Physician Signature: _____ Date (mm-dd-yyyy)

Appendix 6

Sample letter from a TB program to a new arriver with a B notification waiver

[Insert Health Department Logo]

Date :

Dear :

Welcome to name of state!

We have been notified by the Division of Global Migration and Quarantine through the **Bureau of Immigration and Customs Enforcement**¹ that you are now residing in name of jurisdiction and we are **requiring** that you have a medical evaluation for tuberculosis within the next two weeks.

Please report to the **Tuberculosis Clinic**, address for clearance of your tuberculosis waiver on date at time.

Our clinic hours are:

clinic hours

Please bring this letter, all x-ray films and any medical forms that you have with you.

If you have already reported to this clinic or if you need to change your appointment, please call phone number.

Sincerely,

Name of Sender

Title of Sender

Name of TB Control Program

¹ Formerly the INS

Appendix 7

National Indicators

Sentinel indicators

Used to measure significant breakdown in the Class A/B notification system. A protocol should be developed for notifying the Division of Global Migration and Quarantine of these events, as they occur. These sentinel events should prompt a trace-back of the overseas medical examination to determine how these events could be minimized, or eliminated, in the future.

Notification indicators

Used to assess the timeliness and completeness of providing notifications to state and local health jurisdictions.

Follow-up evaluation indicators

Used to assess the timeliness and completeness of performing follow-up evaluations by state and local health jurisdictions.

Outcome indicators

Used to assess the contribution of class A/B1/B2 arrivals to the total burden of treatment of disease and infection, as per American Thoracic Society (ATS) TB Classification 2,3, or 4, and were started on therapy.

Appendix 8

National Objectives for Domestic Follow-up/Evaluation and Outcome Indicators

- I. At least 90% of persons entering the jurisdiction with Class A or B1 TB will receive an initial evaluation for TB disease/infection within one month of receipt of B notification.
- II. At least 90% of Classes A and B1 – B3 will have domestic TB evaluation form (EDN worksheet) submitted to TBCB (or entered into EDN) within 90 days of arrival.
- III. At least ____% of persons entering the jurisdiction with Class A/B1 TB who have inactive disease (TB4) and who are eligible for treatment of latent infection will start treatment.
- IV. At least ____% of persons entering the jurisdiction with Class A/B1 TB who have inactive disease (TB4) and who initiate treatment of latent infection will complete it.
- V. At least ____% of persons entering the jurisdiction with Class A/B1 TB who are infected without disease (TB2) and who are eligible for treatment of latent infection will start treatment.
- VI. At least ____% of persons entering the jurisdiction with Class A/B1 TB who are infected without disease (TB2) and who initiate treatment of latent infection will complete it.

Appendix 9

Outcome Reporting: Recommended Documentation

1. Date notification received
2. Date person arrived in the U.S.
3. Name/age/country of origin/address/telephone number
4. Alien number - The Immigration and Naturalization Services alien number
5. Type of notification (A, B1, B2 or B3)
6. Date of initial medical evaluation in the U.S.
7. Number of days from arrival date to date of initial evaluation
8. Final ATS class
9. Time to complete evaluation
10. Report finalized and submitted to TBCB/CDC